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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2726]

Medical Devices; Draft Guidance on Labeling For Laboratory Tests; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled '' Draft Guidance on Labeling for Laboratory Tests. " This draft guidance is not final nor is it in effect at this time. The draft guidance is intended to identify the information that should be provided to FDA for labeling the diagnostic performance of laboratory tests. FDA intends to recognize two major categories of endpoints for assessing diagnostic performance of new "in vitro diagnostic" assays.

DATES: Written comments concerning this draft guidance must be received by (insert *date 90 days after date of publication in the* **Federal Register).**

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Draft Guidance on Labeling for Laboratory Tests" to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301--443-8818.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–.305), Food and Drug Administration, 5630 Fishers Lane, rrn. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594-3084.

SUPPLEMENTARY INFORMATION:

I. Background

The labeling and evaluation of laboratory test performance should compare a new product's test results to some appropriate and relevant diagnostic benchmark that can be used to correlate results from a new test with the clinical status or condition of individuals or patients for whom the test is intended to be used. Determination of the clinical status of patients whose specimens are used in an evaluation may be based on laboratory and/or clinical endpoints. FDA recognizes two major categories of endpoints for assessing performance of new laboratory assays: (1) "Tree" diagnostic state (patient clinical status or condition) or operational "truth," and (2) laboratory equivalence where the test is characterized in terms of a comparison to a legally marketed predicate.

This draft guidance represents the agency's current thinking on labeling of diagnostic performance for new laboratory tests. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance is issued as a Level 1 guidance consistent with GGP's.

II. Electronic Access

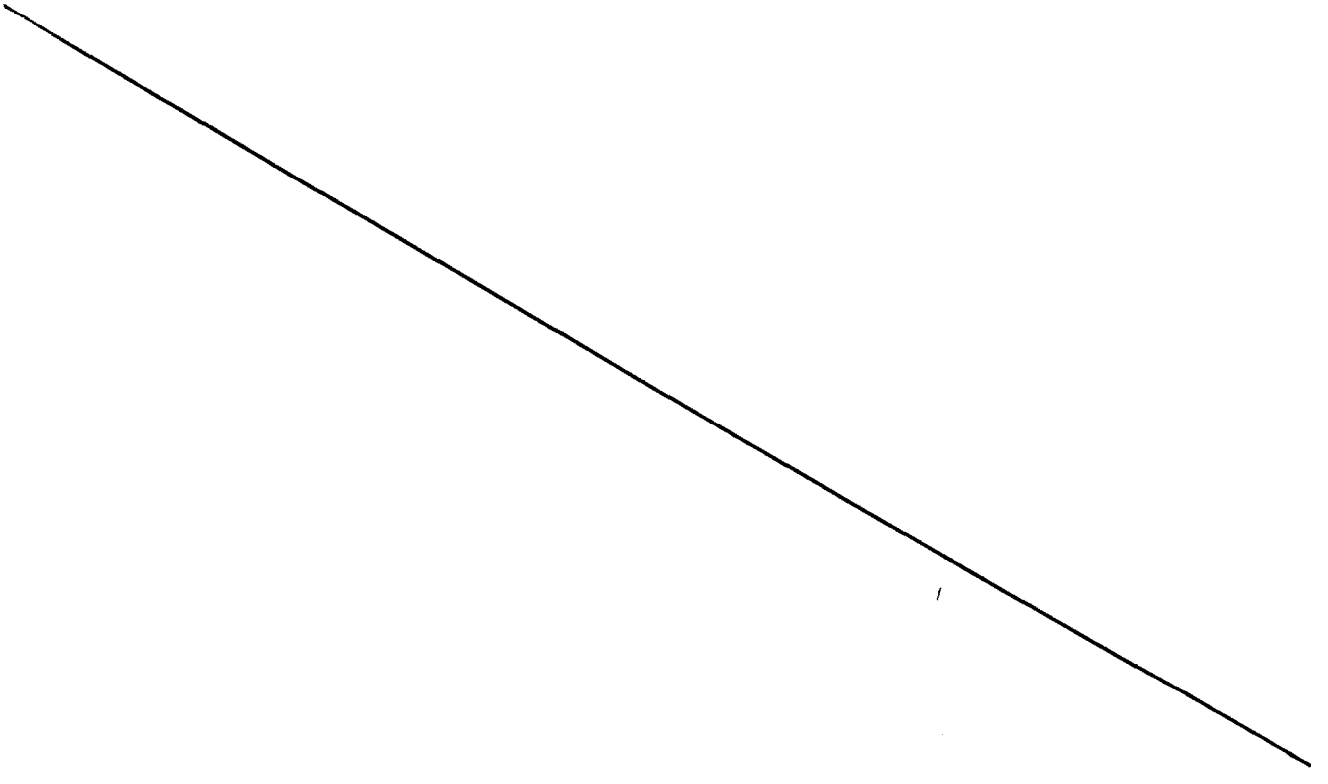
In order to receive the "Draft Guidance on Labeling for Laboratory Tests" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301–827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice

prompt press 2, and then enter the document number (1352) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the "Draft Guidance on Labeling for Laboratory Tests, " device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ' 'http://www.fda. gov/cdrh".

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number



found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/24/99

August 24, 1999

Linda S. Kahan
Deputy Director for
Regulations Policy
Center for Devices and
Radiological Health

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

[FR Dec. **99-????** Filed ??-??-99; 8:45 am]

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